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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
ACSES 65470	

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on May 1, 2006

Signature

Typed or printed name Thomas H. Majcher

Application Number	Filed
10/662,697	9/15/03

First Named Inventor: William J. Boyle

Art Unit	Examiner
3731	Sarah K. Webb

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 31,119
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34

Signature

Thomas H. Majcher
Typed or printed name

(310) 824-5555
Telephone number

May 1, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Tradeamrk Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/662,697
Applicants	:	William J. Boyle et al.
Filed	:	September 15, 2003
Title	:	DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR EMBOLIC PROTECTION DEVICES
Art Unit	:	3731
Examiner	:	Sarah K. Webb
Docket No.:	:	ACSES-65470 (2309D)
Customer No.	:	24201

Los Angeles, California
May 1, 2006

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Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates generally to filtering devices used to capture embolic material that may be created and released into a body vessel when an interventional procedure is being performed in a stenosed or occluded region of the body vessel. The present invention is more particularly directed to recovery systems for recovering and removing these filtering devices from the body vessel after the procedure has been performed.

The recovery system of the present invention utilizes an inner catheter capable of being introduced over a guide wire, along with a recovery sheath which extends co-axially over the inner catheter. Control handles are attached to the proximal ends of both the inner catheter and recovery sheath. The inner catheter and recovery sheath are simultaneously advanced over the guide wire to collapse and recover the deployed filtering device located at the distal end of the guide wire.

The inner catheter includes a distal portion made from a length of flexible tubing. This distal portion remains uncovered by the recovery sheath and extends away from the distal end of the recovery sheath when the inner catheter and recovery sheath are advanced along the guide wire. After the inner catheter reaches the filtering device in the body vessel, the recovery sheath can be advanced

distally to "track" over the distal portion of the inner catheter to collapse and draw the filtering device into the recovery sheath.

This distal portion of the inner catheter provides several advantageous features to the recovery system. The distal portion can be made from a highly flexile material which is less likely to cause the body vessel to straighten as it is advanced over the guide wire to retrieve the filtering device. The length of tubing forming the distal portion provides a "track" over which the recovery sheath moves once the inner catheter reaches the filtering device. This smaller diameter distal portion actually helps to maintain the curvature of the body vessel by minimizing the possibility of the artery will "straighten" as the larger diameter recovery sheath is advanced over the distal portion and the deployed filtering device. This feature is particularly useful when the recovery system is being deployed on a curved portion of the body vessel. Additionally, the increased flexibility of the distal portion better enables the catheters to more easily negotiate the often tortuous anatomy of the vasculature and improves tracking over the guide wire.

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of December 22, 2005 is being filed concurrently herewith along with the appropriate fee.

ISSUES ON APPEAL

At issue is whether claims 35-40, 42-50, 52-74 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). A secondary issue is whether dependent claims 41 and 51 are obvious under 35 U.S.C. § 103(a) over the Daniel patent in view of U.S. Patent No. 5,201,757 to Heyn et al. ("the Heyn patent"). The Daniel patent is directed to a system for recovering a filter device disposed at the end of a guide wire. The Daniel recovery system includes an inner catheter 172 and a retrieval catheter 150 having an enlarged housing 152 for storing the collapsed filter. The inner catheter 172 includes a transversely enlarged portion 176 which fills the inside diameter of the housing 152 in order to create an atraumatic tip. This portion 176 has a short tapered portion 180 which barely extends out of the housing 152. This short tapered portion 180 creates a smooth tapered tip profile and helps to prevent the distal end 157 of the housing 152 from "snowplowing" into the wall of the body vessel as the catheter is advanced over the guide wire.

A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. A copy of the final Office Action dated December 22, 2005 is attached hereto as Exhibit C. The Daniel patent is attached as Exhibit D. The Heyn patent is attached as Exhibit E. The Advisory Action dated April 22, 2006 is attached as Exhibit F.

ARGUMENT

Claims 35-53, 63-66 and 68-74 are apparatus claims directed to a system for recovering an embolic protection device. Claims 54-62 and 67 are method claims directed to a method for recovering the embolic protection device. Each claim includes the recitation of an inner catheter having a distal portion including a length of flexible tubing capable of being loaded within a recovery sheath. Each claim also requires the distal portion of the inner catheter to extend distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are advanced over a guide wire with the distal portion of the inner catheter having sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed.

Claims 35-40, 42-50, 52-74 were rejected under 35 U.S.C. § 102(e) as being anticipated by the Daniel patent. Appellant submits that the Examiner has misinterpreted the Daniel patent, has relied on an embodiment (Fig. 19) in the Daniel patent in rejecting claims which lacks the basic structure recited in the present claims, and has misconstrued the pending claims by disregarding specific structural recitations appearing in the claims.

One main issue in dispute is whether the small tapered tip 180 located at the distal end of the inner member 150 of the Broome patent constitutes a "length of flexible tubing" having sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel. Initially, the Examiner had taken the position that this short tapered portion 180 meets the structural requirements of each claim because it is part of the catheter and is a flexible tube. Appellant has consistently argued that the claims require more that just a length of tubing extending out of the recovery sheath since the claims also require the distal portion to have a length of flexible tubing having sufficient length to allow the distal end of the recovery catheter to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel. Apparently, the Examiner has given little or no consideration for this structural limitation recited in each claim. Appellant has argued that the inner catheter 172 in FIG. 20 or component 372

in FIG. 23 of the Daniel patent includes only a small tapered portion 180 which barely extends beyond the recovery sheath 150 and does not constitute a distal portion of the inner catheter as this component is defined in the claims. This distal tapered portion 180 is simply the end of a large insert 176 designed to fill the lumen of the recovery sheath's housing and provide a soft and atraumatic tip. This portion 176 remains within the lumen of the housing during usage with only a small portion of the tapered portion 180 extending beyond the distal end of the recovery sheath.

Appellant submits that if this distal tip portion 180 is construed to be a "length of tubing," as the Examiner contends, then it must be capable of allowing the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel. This structural recitation in the claims cannot be disregarded. Due to its tapered structure, this tapered portion 180 doesn't even make contact with the retrieval catheter 150. Appellant submits that it cannot and does not function as a track over which the recovery sheath moves to reduce the possibility that the retrieval catheter will straighten a curved portion of the body vessel.

In the last Office Action, the Examiner has taken the additional position that the distal portion of the inner catheter is more than just this tapered tip portion 180. The Examiner's new position, found at page 6, lines 1-7 of the final Office Action (Exhibit C), reads as follows:

> Examiner does not consider only the tip of the inner catheter to be the distal portion of the inner catheter. The "distal portion" can be any length of the inner catheter distal to the most proximal point. Therefore, the Daniels device includes a length of the inner catheter that is at least as long as the filter. The "recovery sheath does "move over" the entire inner catheter, so this argument is not found to be persuasive.

However, the only portion of the inner catheter which arguably could be construed as a flexible tube is the portion of the inner catheter which extends proximally, not distally, to the tip portion 176. In use, this portion of the inner catheter in the Daniels device remains completely covered by the recovery sheath. Again, the claims recite that the distal portion of the inner member remains distal of the distal end of the recovery sheath when advanced along the guide wire.

The error in the Examiner's position is further found in statements made in the Advisory Action dated April 22, 2006 (Exhibit F). The Examiner states as follows:

> Clearly a length of this tube (172) extends distally beyond the sheath (150. The figures show only one of the many possible relevant positions between the components, so the inner tube could be moved to extend farther beyond the sheath.

However, the inner tube could not possibly be moved to extend farther beyond the sheath. Control handles attached to the inner catheter and recovery catheter prevent the inner catheter from extending any further than is shown in Figures 20 and 23. (See figures 24-26 and Column 9, line 51-Column 11, line 2 of Daniel patent). Therefore, the Examiner's position is incorrect.

The Examiner also has relied on the embodiment of figure 19 to support the position that the recovery sheath tracks over the inner catheter. However, this embodiment lacks the basic inner catheter recited in the claims. At page 2, lines 16-18 of the final Office Action (Exhibit C), the Examiner states the following:

> The recovery sheath (151) tracks over the distal portion on the inner catheter to retrieve the filter, as shown in Figure 19.

However, this embodiment doesn't have an inner catheter, no less an inner catheter with a distal portion made from a length of flexible tubing. The embodiment of figures 19 simply shows a tapered insert 58 attached to a guide wire which is movable within the housing 52 of the recovery catheter.

Claims 41 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent in view of the Heyn patent. Since the Daniel patent lacks the basic components recited in the claims, its combination with the Heyn patent fails to achieve the structure recited in the claims.

In summation, the Daniel patent simply fails to disclose the presently claimed invention. It is therefore urged that claims 35-74 are allowable over the cited art.

Respectfully submitted,

FULWIDER PATTON LLP

By: _____

Thomas H. Majcher
Registration No. 31,119

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201

U.S. Patent Application Serial No. 10/662,697 filed September 15, 2003
DEPLOYMENT AND RECOVERY CONTROL SYSTEMS FOR
EMBOLIC PROTECTION DEVICES
Inventors: William J. Boyle, et al.
ACS Ref. No.: 2309D
Our Docket No.: ACSES-65470

Claims as of Final Office Action

1 – 34 (Canceled).

35. (Previously presented) A system for recovering an embolic protection device which includes a guide wire and expandable filter disposed thereon from a body vessel, comprising:

an inner catheter having a distal portion and a proximal end and being moveable along the guide wire, the distal portion including a length of flexible tubing;

a control handle attached to the proximal end of the inner catheter;

a recovery sheath having a distal end and a proximal end; and

a control handle attached to the proximal end of the recovery sheath, wherein the inner catheter is capable of being loaded inside the recovery sheath with the distal portion of the inner catheter extending distally beyond the distal end of the recovery sheath when the inner catheter and recovery sheath are being advanced along the guide wire for placement in proximity to the expandable filter of the embolic protection device, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

36. (Original) The system of claim 35, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

37. (Original) The system of claim 35, wherein:

the recovery sheath has greater column strength than the inner catheter.

38. (Original) The system of claim 35, wherein:

the inner catheter has greater column strength than the recovery sheath.

39. (Original) The system of claim 35, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

40. (Original) The system of claim 35, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

41. (Original) The system of claim 35, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

42. (Original) The system of claim 41, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

43. (Original) The system of claim 42, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath.

44. (Original) The system of claim 35, further including:

means for locking the inner catheter onto the guide wire.

45. (Previously presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes length of flexible tubing; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

46. (Original) The system of claim 45, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

47. (Original) The system of claim 45, wherein:

the recovery sheath has greater column strength than the inner catheter.

48. (Original) The system of claim 45, wherein:

the inner catheter has greater column strength than the recovery sheath.

49. (Original) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

50. (Original) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

51. (Original) The system of claim 45, wherein:

the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

52. (Original) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

53. (Original) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.

54. (Previously presented) A method of re covering an embolic protection device which includes a guide wire and an expandable filter from a body vessel, comprising:

loading an inner catheter inside a recovery sheath, wherein the inner catheter has a distal portion which extends beyond the distal end of the recovery lumen, the distal portion including a length of flexible tubing having sufficient length to allow the distal end of a recovery sheath to pass thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel;

introducing the inner catheter and recovery sheath over the guide wire;

advancing the distal end of the inner catheter to a position adjacent to the expanded filter;

locking the inner catheter onto the guide wire;

tracking the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

55. (Original) The method of claim 54, further comprising:

removing the recovery sheath, inner catheter, and embolic protection device from the body vessel.

56. (Original) The method of claim 54, wherein:

the recovery sheath may be up to approximately 15 centimeters shorter than the inner catheter.

57. (Original) The method of claim 54, wherein:

the distal portion of the inner catheter may extend up to 10 centimeters beyond the distal end of the recovery sheath when being advanced over the guide wire.

58. (Original) The method of claim 54, wherein:

a control handle is located at the proximal end of the inner catheter and a control handle located at the proximal end of the recovery sheath.

59. (Original) The method of claim 58, wherein:

the control handle of the inner catheter can be locked to the control handle of the recovery sheath.

60. (Original) The method of claim 54, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the proximal end of the inner catheter to lock the inner catheter onto the guide wire.

61. (Original) The method of claim 58, wherein:

after the distal end of the inner catheter is advanced to a position adjacent to the expanded filter, a torque control device is attached to the guide wire and placed in an abutting relationship with the control handle of the inner catheter to lock the inner catheter onto the guide wire.

62. (Original) The method of claim 58, wherein:

control handle of the recovery sheath is advanced distally to position the recovery sheath over the distal portion of the inner catheter and the expanded filter to collapse the expanded filter.

63. (Previously Presented) The system of claim 35, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

64. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

65. (Previously Presented) The system of claim 45, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

66. (Previously Presented) The system of claim 35, wherein:

the flexible tubing of the distal portion of the inner catheter is more flexible than the recovery sheath.

67. (Previously Presented) The method of claim 54, wherein:

the recovery sheath is adapted to track over at least a portion of the flexible tubing of the distal portion of the inner catheter.

68. (Previously Presented) An embolic protection system for deployment in a body vessel, comprising:

a guide wire having a distal end;

an expandable filter having a particular longitudinal length located near the distal end of the guide wire;

an inner catheter having a distal portion and a control handle located at a proximal end, wherein the inner catheter is capable of being introduced over the guide wire and the distal portion includes a length of flexible tubing at least al long as the longitudinal length of the expandable filter; and

a recovery sheath having a distal end and a control handle located at a proximal end, wherein the inner catheter is capable of being loaded inside of a lumen of the recovery sheath, wherein the distal portion of the inner catheter extends distally beyond the distal end of recovery sheath when being advanced along the guide wire to retrieve the expandable filter, the recovery sheath having sufficient column strength to collapse the expandable filter when advanced over the expandable filter and the distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel.

69. (Previously Presented) The system of claim 68, wherein:

the recovery sheath may be up to 15 centimeters shorter than the inner catheter.

70. (Previously Presented) The system of claim 45, further including:

a locking mechanism for locking the control handle of the inner catheter with the control handle of the recovery sheath.

71. (Previously Presented) The system of claim 45, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

72. (Previously Presented) The system of claim 45, wherein:

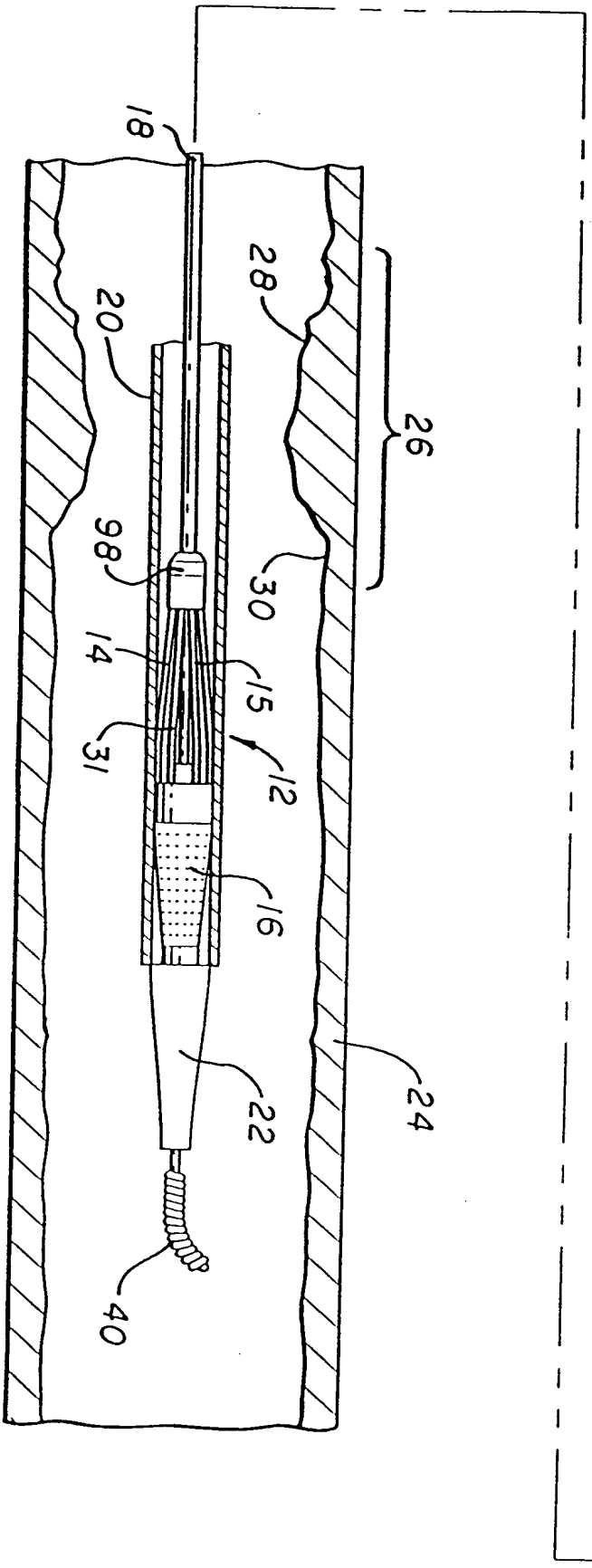
the control handle of the inner catheter is coaxially disposed within a lumen of the control handle of the recovery sheath.

73. (Previously Presented) The system of claim 51, wherein:

the control handle of the inner catheter can be locked with the control handle of the recovery sheath.

74. (Previously Presented) The system of claim 52, wherein:

the control handle of the inner catheter is movable relative to the control handle of the recovery sheath and further including means for locking the control handles together.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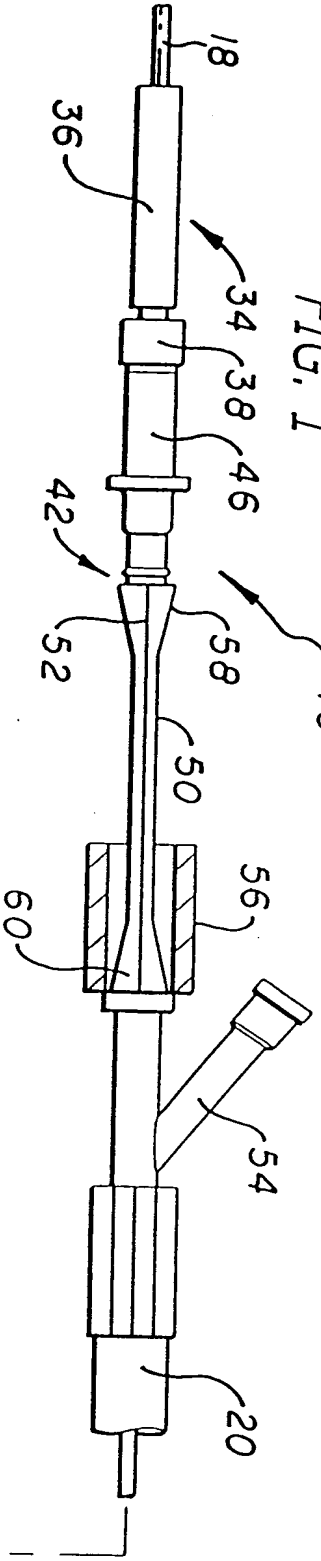
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FIG. 1

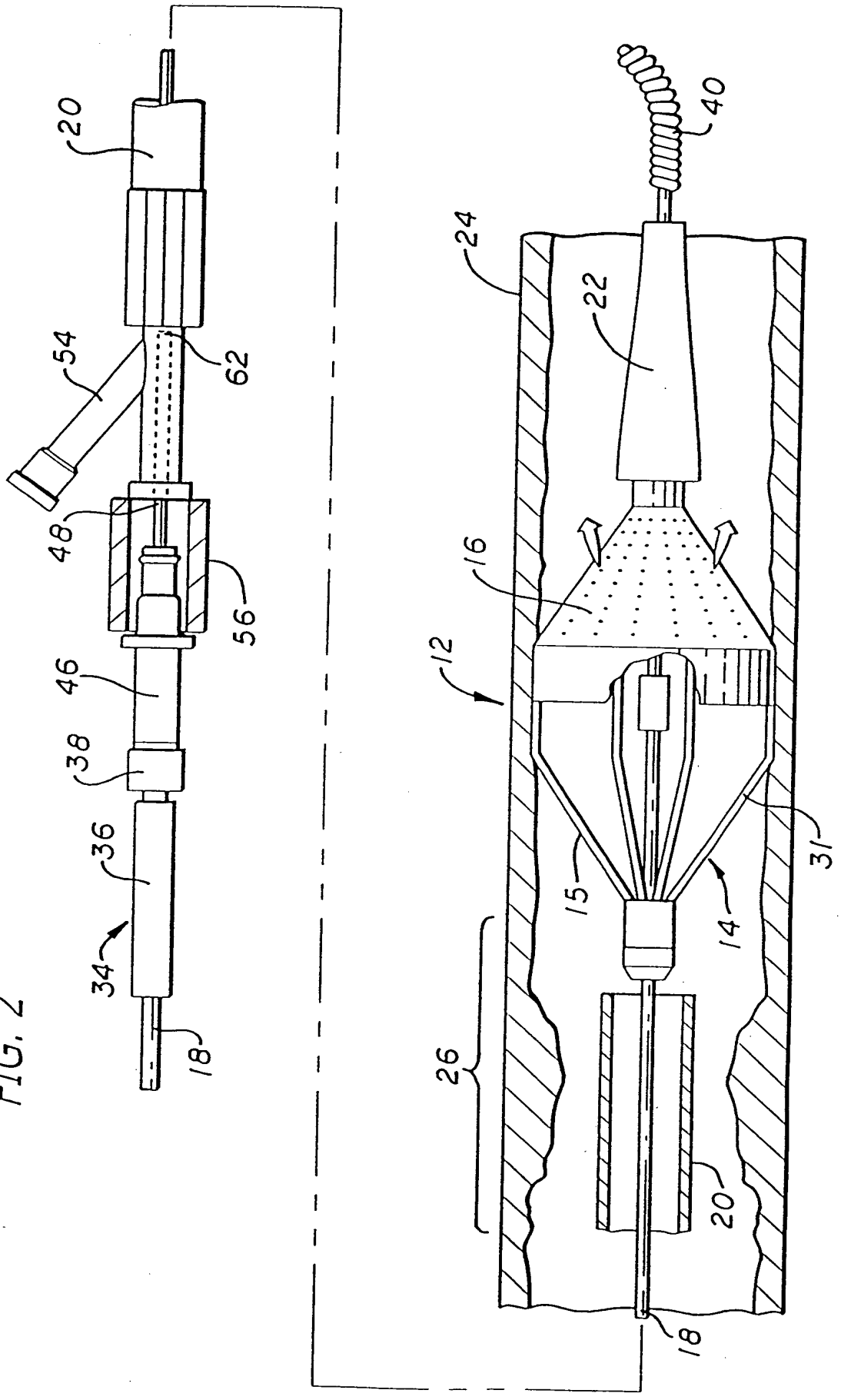

FIG. 2

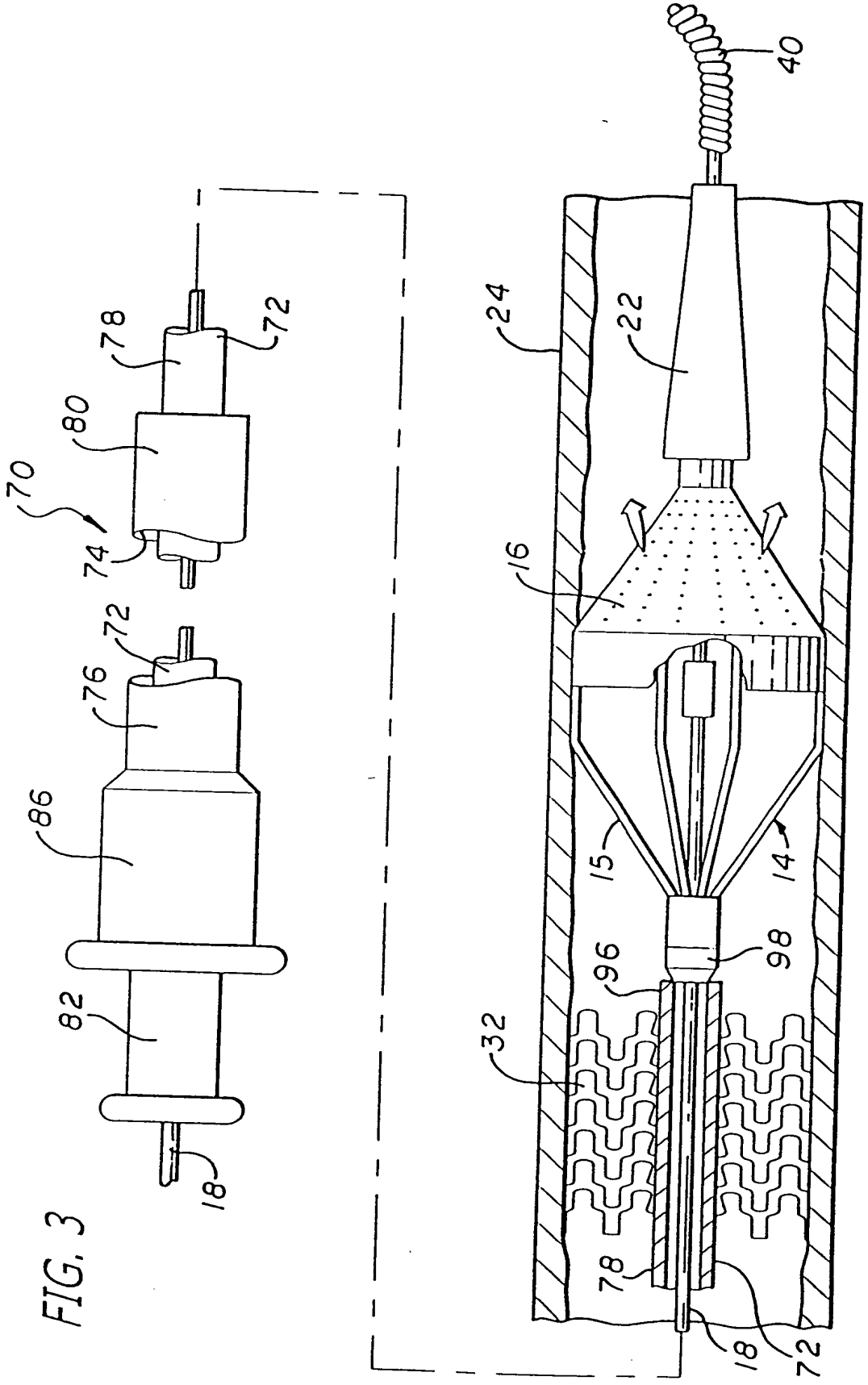

FIG. 3

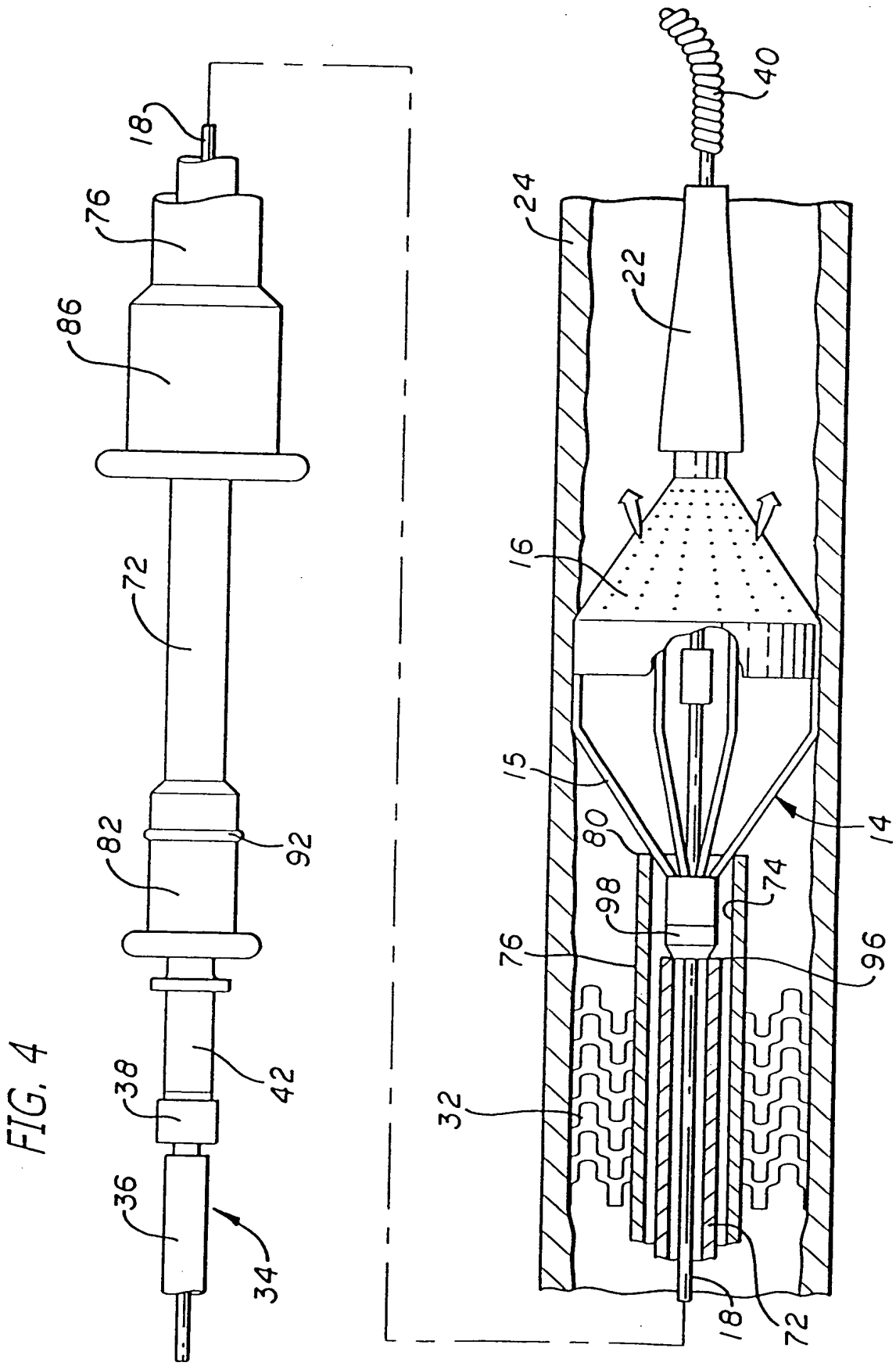

FIG. 4

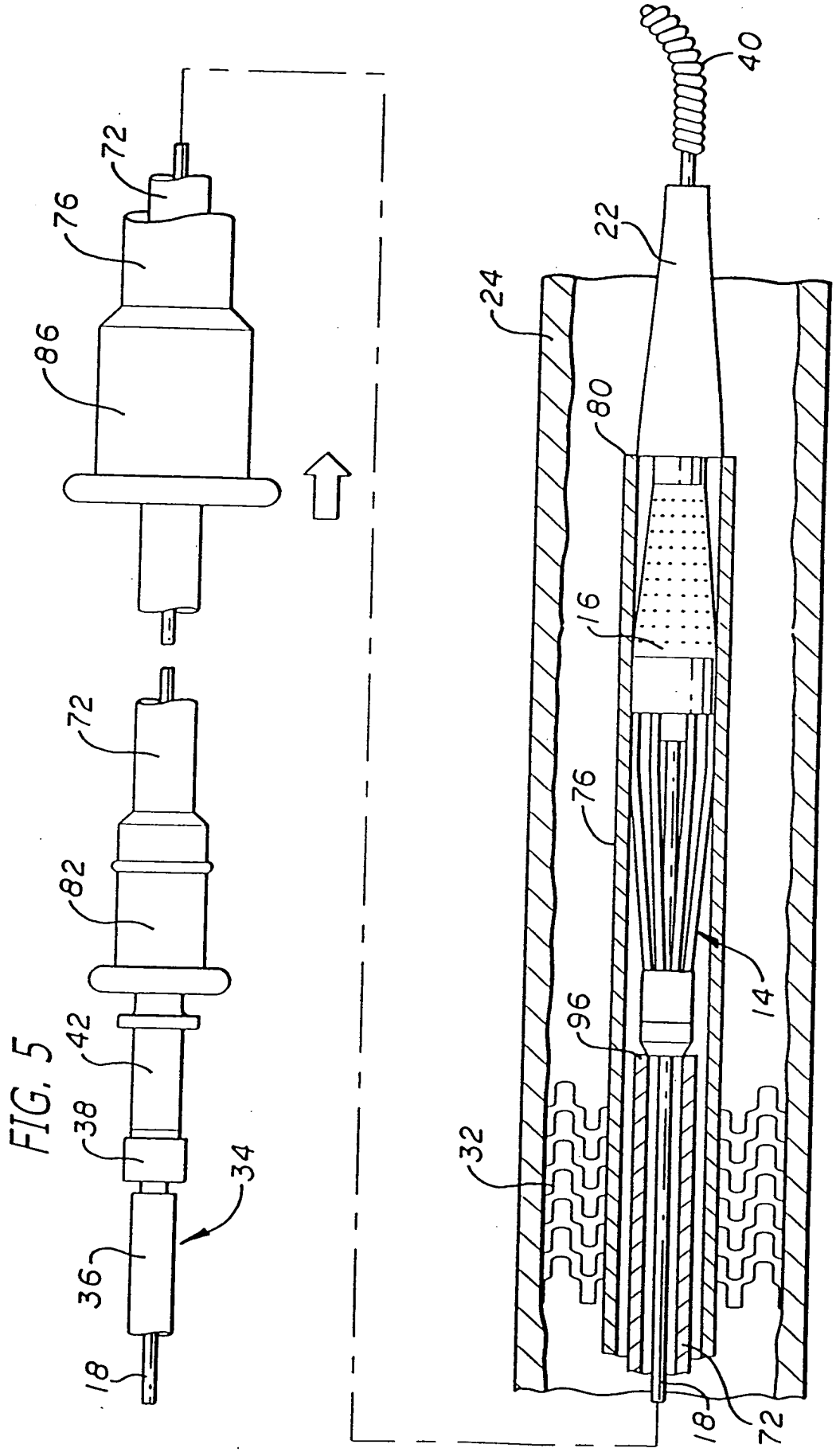

FIG. 5

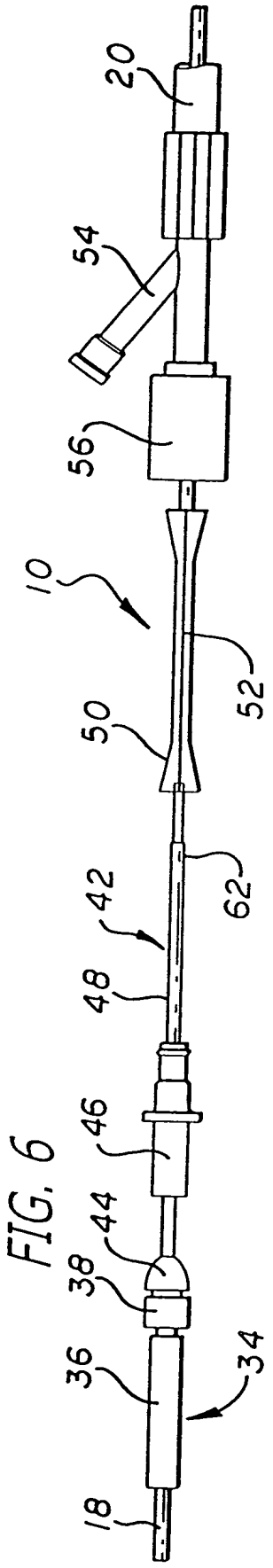

FIG. 6

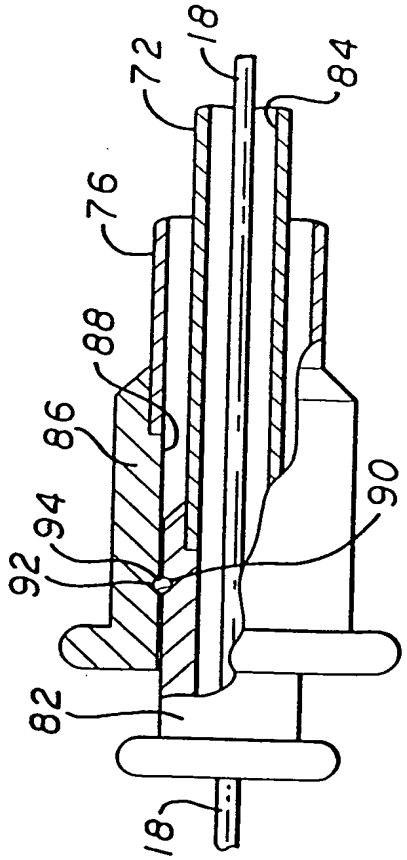

FIG. 7

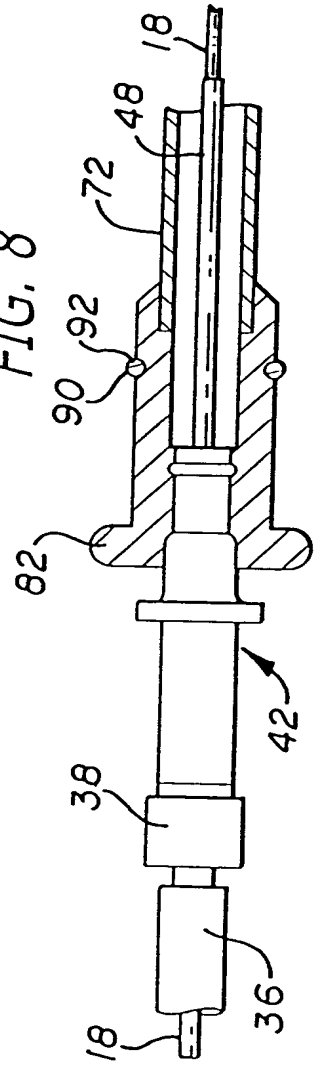

FIG. 8

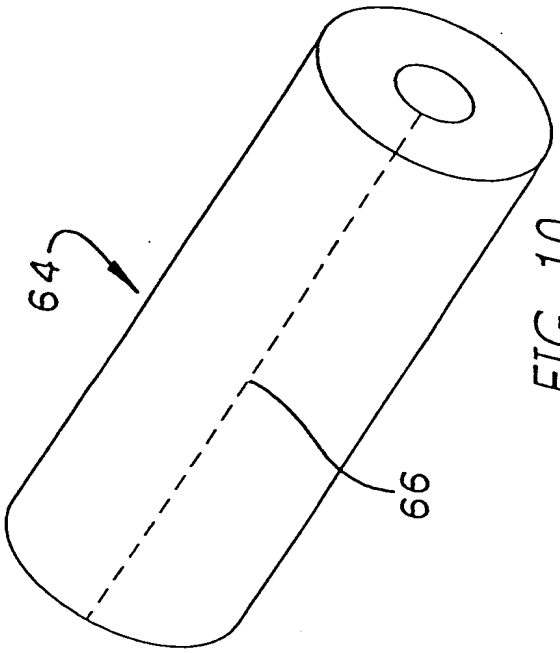

FIG. 10

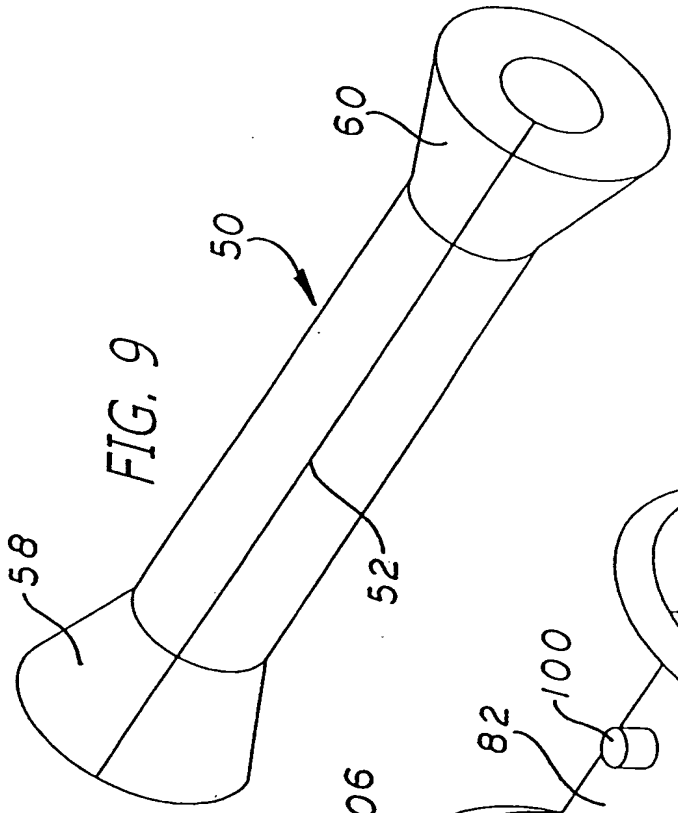

FIG. 9

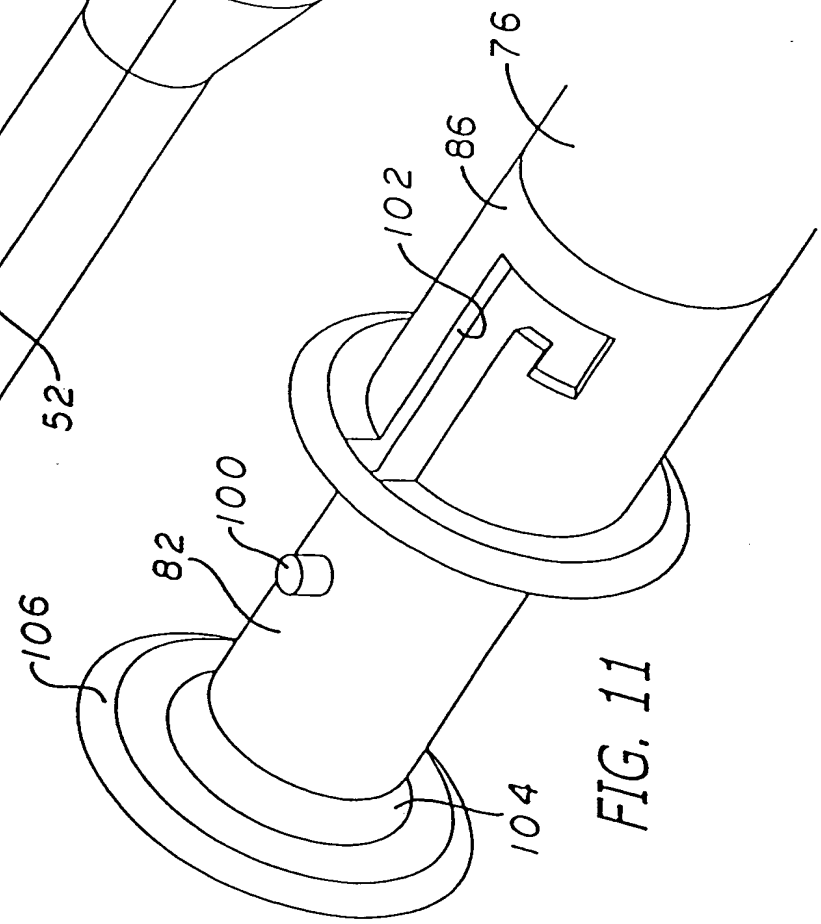

FIG. 11

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,697	09/15/2003	William J. Boyle	ACS 65470 (2309D)	9777

24201 7590 12/22/2005

THM

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
WEBB, SARAH K	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: February 22, 2006
3 - MONTH RESPONSE DUE: March 22, 2006
NOTICE OF APPEAL DUE:
(6-MONTH PERIOD ENDS) June 22, 2006

Office Action Summary	Application No.	Applicant(s)	
	10/662,697	BOYLE ET AL.	
	Examiner	Art Unit	
	Sarah K. Webb	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 10/11/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,569,184 to Huter has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 35-40,42-50, and 52-74 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniels illustrates a catheter system in Figures 20-23 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20 or 372 in Figure 23) that extends distally beyond a recovery sheath (151). Claims 36,46,56,57 are significantly broad enough to encompass any length of either catheter. The recovery sheath (151) tracks over the distal portion of the inner catheter to retrieve the filter, as shown in Figure 19. Daniels explains that the distal portion of the inner catheter is made of flexible material (column 8, lines 61-67). As evidenced by the fact that the recovery sheath (151) is capable of deforming the distal end (180,280) of the inner catheter when pushed distally to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151). Each catheter has a control handle attached to its proximal end, and the handles are illustrated in Figures 24-26. Control handle

702 is connected to the proximal end of the recovery sheath (151) and control handle 710 is connected to the proximal end of the inner catheter (372).

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language *"may be up to"*, *"may be up to approximately"*, and *"may extend up to"* is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially

disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

4. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. Daniels fails to state that the inner catheter has greater column strength than the recovery sheath. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to form the inner catheter to have greater column strength than the recovery sheath, because applicant has not disclosed that the combination of these material properties provide an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the combination of material properties disclosed by Daniels, because the Daniels device achieves the same objective of tracking a recovery sheath over an inner catheter to retrieve a filter.

Response to Arguments

5. Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. Applicant argues that the recovery sheath does not "track" over the distal portion of the inner catheter (172) because the distal tip of the catheter is

tapered. The distal portion (172,180) is part of the inner catheter, which is a flexible tube. Examiner does not consider only the tip of the inner catheter to be the distal portion of the inner catheter. The "distal portion" can be any length of the inner catheter distal to the most proximal point. Therefore, the Daniels device includes a length of the inner catheter that is at least as long as the filter. The recovery sheath does "move over" the entire inner catheter, so this argument is not found to be persuasive.

6. Applicant argues that the distal portion of the inner catheter of the Daniels device does not *"reduce the possibility that the recovery sheath will straighten the body vessel..."* Daniels is not required to explicitly state this characteristic of the device. Daniels is only required to meet the structural requirements of the claims. Claim 35 recites *"inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility..."* The claims nor the specification set forth any further characteristics that a device must have in order to be capable of this function. Since Daniels includes all of the structural requirements of the claims, Daniels is considered to meet the claim limitations.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
12/19/05

JULIAN W. WOO
PRIMARY EXAMINER

MAR 31 2006

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,697	09/15/2003	William J. Boyle	ACS 65470 (2309D)	9777

24201 7590 03/29/2006

THM

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
WEBB, SARAH K	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 03/29/2006

Advisory Action

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: _____

3 - MONTH RESPONSE DUE: _____

NOTICE OF APPEAL DUE:

(6-MONTH PERIOD ENDS) June 22, 2006

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/662,697	**Applicant(s)** BOYLE ET AL.	
	Examiner Sarah K. Webb	**Art Unit** 3731	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 February 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments were not found to be persuasive. Applicant asserts that the distal end of the inner tubing does not extend distally beyond the recovery sheath in the Daniel's patent. The embodiment in Figure 20 has an inner cahteter. Clearly, a length of this tube (172) extends distally beyond the sheath (150). The figures show only one of many possible relative positions between the components, so the inner tube could be moved to extend farther beyond the sheath. Even though only a short length of the inner tube is illustrated as extending beyond the sheath (150), the short length meets the broad limitation "a length." The disclosed function of the Daniel's inner tube is irrelevant as long as Daniel's meets the structural requirements.